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UNCLAS BRATISLAVA 000880

SIPDIS

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SUBJECT: SPECIAL 301: SLOVAKIA WORKING TO GET OFF THE 2006 WATCH LIST

REF: BRATISLAVA 161

¶1. SUMMARY: The Government of Slovakia has held two meetings in recent months with pharmaceutical companies and Embassy representatives aimed at addressing outstanding Special 301 issues so that Slovakia can be removed from the USTR "Watch List" in 2006. The relevant GOS ministries are saying the right words and have proposed solutions to the two main issues - procuring a secure storage facility for sensitive registration data and development of a coordination mechanism between the Drug Control Office and the Patent Office - but need to follow their promises with action. A USTR-hosted DVC in early December would provide a venue for USG interlocutors to assess progress to date and encourage the GOS to take verifiable steps before decisions are taken for the 2006 Special 301 Report. End Summary.

¶2. At the urging of the Slovak Embassy in Washington, the Ministry of Economy has hosted two "stakeholders" meetings (July 8 and October 20) to address the outstanding pharmaceutical issues listed in the 2006 Special 301 report. The meetings brought together Embassy representatives, the Amcham Local Area Working Group (LAWG), which is a collection of research-based pharmaceutical companies in Slovakia, and the relevant GOS agencies including the Ministry of Health (MOH), Drug Control Office, Industrial Property (patent) Office, Ministry of Foreign Affairs, Prime Minister's Office, Customs Directorate, and Trade Inspection Agency.

¶3. After an initial unwillingness to acknowledge inadequacies in its IPR regime, the GOS has come around and now recognizes that it must address the outstanding Special 301 issues before Slovakia can be removed from the Watch List. The "stakeholder meetings" created intra-ministerial working groups that have come up with proposals for the two key issues outlined in the 2005 report:

STORAGE OF PROPRIETARY DATA: The Drug Control Office (DCO) has stored sensitive registration data on the premises of a generic drug producer for years. Minister of Health Rudolf Zajac recently promised to provide funds for DCO to secure a storage facility to house proprietary data. DCO initially floated a tender to lease a storage facility, but due to the high cost of the bids DCO is now looking to purchase a storage facility. Zajac has promised to finalize the transaction by the end of the year, with the goal of moving the registration documents to a new facility in 2006.

REGISTRATION OF GENERICS: In several cases over recent years the Drug Control Office has approved applications for registration by generic manufacturers for drugs that are still under patent protection because it has failed to check the status of the original patent with the patent office. Once a registration is granted to a generic manufacturer, it is very difficult for the patent owner to overturn the decision or obtain compensation through the courts. The Drug Control and Patent offices have proposed a coordinating mechanism to prevent future registrations of unauthorized patent-infringing products. Although LAWG considers this an improvement to the status quo, they would like the Drug Control Office to notify the patent holder when they receive a request from a generic manufacturer to add a degree of transparency to the process. The relevant GOS ministries promised during the October meeting to consider the LAWG proposal and discuss it with them in mid-November.

¶4. LAWG is also using the stakeholder meetings to push for improvements on non-IPR market access for pharmaceutical companies. They complain that a recent Ministry of Health decree (No. 723/2004), which was published in July and went into effect on October 15, 2005, further reduces the transparency of GOS decisions regarding pricing and reimbursement decisions for medicines prescribed by national health insurance. The decree specifies the rules to be applied in determining the price of the medicinal product and level of reimbursement. The original decree provided detailed rules for calculation of the price and level of

reimbursement. However, recent amendment of the decree cancelled the detailed rules for determination of the reimbursement amount and, instead, provided the Ministry of Health with a wide scope of discretion to decide on the amount of reimbursement without setting a clear set of guidelines for such decisions. LAWG complains that the new regulation increases the subjectivity of the Board's decision-making, and thus minimizes the predictability and transparency of the process.

¶5. COMMENT: During the October meeting the relevant GOS ministries needed less than 45 minutes to agree on proposals to address the patent issues that have kept Slovakia on the Watch List for several years. The trick now is to ensure that the GOS follows through with verifiable actions before final decisions are made for the 2006 report. As a next step we recommend a USTR-hosted digital video conference with the relevant GOS officials (the Embassy will host the GOS participants in our DVC facilities) to assess progress to date and encourage quick action to fulfill their promises. A DVC sometime between November 28 and December 9 should provide the GOS with sufficient time to finalize negotiations with LAWG, while simultaneously providing a large enough window to implement their proposals before the 2006 301 review.

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